PCN118

TASTE DYSFUNCTION AFTER HEAD AND NECK CANCER TREATMENT: A META-ANALYSIS

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OBJECTIVES: Taste dysfunction is a common, debilitating problem for head and neck cancer treatment survivors (HNCTS). When taste is impaired eating is not as enjoyable, appetite is diminished and overall health related quality of life (HRQoL) is diminished. However, the extent to which taste impairment in HNCTS remains altered over time is not well understood. **METHODS:** The Ovid MEDLINE®, SCOPUS, and CINAHL data bases were searched for reports of HNCTS in which taste function was measured. Eligible studies compared taste scores baseline to up to five years post treatment. 3872 reports were identified in the literature search and 20 studies were suitable for inclusion in the final analysis. Estimates of effect size of head and neck cancer therapy on taste dysfunction were extracted from each study. A descriptive meta-analysis was conducted using Comprehensive Meta-analysis software (Version 2, Biostat, Englewood, NJ). **RESULTS:** The meta-analysis included data on 1526 subjects. The sample was predominantly young in age (mean age is 59.11 years) and 66.8% male. Head and neck cancer treatment survivors reported statistically significantly worse taste scores 6 months or longer after completing all cancer treatment. The summary effect for the standard measure difference between pretreatment and post-treatment taste scores was 0.331 (p=<0.001). The sample was highly heterogeneous in terms of country, tumor site, and therapy, so a random effects model was chosen for data analysis. Heterogeneity testing supported this decision (Q=82.08, df 18, p < 0.001). **CONCLUSIONS:** Assessment of HRQoL in HNCTS should include questions on taste function. With the global increase in HPV related head and neck cancers, the pool of treatment survivors is expected to increase over the next decade. The Taste dysfunction is a long-term complication for HNCTS and clinicians should screen survivors for this sensory dysfunction.

PCN119

THE EMERGING ROLE OF PATIENT-REPORTED OUTCOMES (PROS) IN FDA HEMATOLOGY AND ONCOLOGY PRODUCT LABELS

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OBJECTIVES: The US Food and Drug Administration (FDA) did not approve any PRO label claims for cancer treatments between 2006 and 2010. In December 2009, the agency published guidance on the use of PROs to support label claims, and in 2012 the Center for Medical Technology Policy (CMTP) called for all prospective comparative studies of oncology drugs in adults to include PRO measures. The current study sought to identify how many PRO claims have been approved since the publication of these documents, to consider the challenges for sponsors seeking such claims, and offer solutions to these challenges. **METHODS:** The FDA website was searched for approvals of hematology and oncology drugs 2010–2014. The most recently approved labels of eligible products and drug approval packages were reviewed for comments on PRO data. **RESULTS:** Of 64 drug labels suitable for review, two had PRO efficacy claims: ruxolitinib (myelofibrosis) was claimed to improve symptoms, as measured by the Myelofibrosis Symptom Assessment Form; abiraterone acetate (prostate cancer) was claimed to improve pain, as measured by the Brief Pain Inventory (BPI-SF). For crizotinib (NSCLC), PROs were used to support adverse event reporting (vision disorders). The label for brentuximab stated that no improvement in patient-reported symptoms for either indication (Hodgkin lymphoma and anaplastic large cell lymphoma) had been established. A further 12 labels stated that there were no data to demonstrate improvement in disease-related symptoms. **CONCLUSIONS:** This review demonstrates the emergence of PRO label claims for oncology products, despite the recent FDA and CMTP guidance PRO data are infrequently documented in FDA-approved oncology labels. Labels increasingly specify when there is an absence of symptom data e.g. brentuximab, carfilzomib, marking a shift in FDAs expectations. Sponsors face challenges such as a lack of validated tumor-specific instruments. A strategic four-step PRO endpoint development process provides a way forward.

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DEVELOPMENT AND CONTENT VALIDITY TESTING OF THE PATIENT-REPORTED OUTCOMES OF FATIGUE IN CANCER (PROOF-C) SYMPTOM SEVERITY ASSESSMENT (SSA)

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OBJECTIVES: Cancer-related fatigue (CaF) is a common symptom of cancer and one that can be burdensome to patients. It is possibly under-reported due to its complex origins, inconsistent definitions and assessment methods. In recent years, no existing measures have been accepted by the US Food and Drug Administration (FDA) to support labeling claims in CaF. The Patient-Reported Outcomes of Fatigue in Cancer (PROOF-C) Consortium have developed the Symptom Severity Assessment (SSA), a patient-reported outcome (PRO) measure of CaF to be aligned with FDA expectations as part of the FDA's Drug Development Tool (DDT) Qualification Program. **METHODS:** In total 91 open-ended concept elicitation (CE) interviews were conducted among eight cancer types to spontaneously elicit the patient experience of CaF. Items were generated based on qualitative, thematic analysis of verbatim transcripts and with input from a clinical expert. Subsequently, 61 cognitive interviews (CIs) were conducted with patients in six cancer types, wherein a "think-aloud" process and targeted debriefing questions were used to assess concept relevance and patients' understanding of the instructions, items, and response options. **RESULTS:** CE data supported the development of a draft, 13-item SSA, measuring eight symptoms of CaF, with a 24-hour recall period and an 11-point numeric rating scale. The results of the 61 CIs confirmed that the draft SSA was interpreted as intended by patients, and assesses concepts relevant to and experienced by patients across all examined cancer types. Minor revisions were made to nine items to improve clarity. One additional item was added to ensure comprehensiveness. **CONCLUSIONS:** The SSA demonstrates strong content validity, assessing relevant CaF concepts in a manner patients understand. Planned future development activities include additional CIs to confirm content validity of the revised, 14-item SSA in an electronic format, followed by an observational study for the development of scoring, item reduction, and psychometric validation.

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PATIENT-REPORTED OUTCOMES (PROS) IN BLADDER CANCER

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OBJECTIVES: To assess frequency and type of Patient-Reported Outcomes (PROs) in studies of bladder cancer. **METHODS:** A search of Citeline's Trialtrove was conducted using the search criteria "Bladder Cancer" as the disease, drugs tested was "any", trial phase was II/III, III, and IV, and included planned, ongoing and completed studies. This resulted in 182 trials. Study design included clinical trials (double-blind, open-label) and observational studies. Start dates ranged from 1985-2014. Trials were excluded if disease type was other than bladder cancer. The remaining 138 trials were reviewed to determine prevalence and type of PROs. **RESULTS:** Only 27 (7.4%) of the studies included PROs as stated in the endpoints section despite bladder cancer being one of the most commonly diagnosed types of cancer in the US, especially among men. For these 27 trials, 9 different PROs were identified, 3 of which were bladder cancer disease specific. A total of 39 PROs were included with a range of 1-2 PROs per study, an average of 1.44 PROs. Thirty-four (87%) of these PROs measured Health-Related Quality of Life (HRQL) and 5 (13%) were symptom-based measures. Within the HRQL measures, 9 (26.5%) were cancer general, 9 (26.5%) were specific to Bladder Cancer, 1 (3%) was generic (e.g., SF-36), and the remaining 15 (44%) were not specified. Among the symptom measures, 3 (60%) were specific to bladder cancer and 2 (40%) were generic. **CONCLUSIONS:** Results indicate that the prevalence of PROs in bladder cancer trials is low compared to other cancers (e.g., ovarian cancer) and other diseases despite their importance in evaluating impact of disease and treatment benefit. The type of PRO most commonly indicated was a bladder cancer disease-specific measure of HRQL. Findings show the need to highlight the value and relevance of patient-reported data to increase incorporation of PROs in bladder cancer trials.

PCN122

PATIENT-REPORTED OUTCOMES (PROS) IN OVARIAN CANCER CLINICAL TRIALS

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OBJECTIVES: To assess use of Patient-Reported Outcomes (PROs) in studies of Ovarian Cancer. **METHODS:** A search of Citeline's Trialtrove was conducted using the search criteria of "Ovarian Cancer" as the disease, drugs tested was "any," and trial phase was II/III, III, and IV. This resulted in 252 trials. Studies were excluded if the disease type was other than ovarian cancer. Study designs were clinical trial and observational studies, and both double-blind and open-label studies were included. Target accrual for all studies was ≥53. Start dates ranged from 1990 to 2014. The remaining 189 trials were then assessed for prevalence and type of PROs. **RESULTS:** Of the 189 studies reviewed, 102 (54%) included PROs. For these 102 trials, a total of 148 PROs were included, and an average of 1.5 PROs were used per study with a range of 1 to 4. A total of 15 different PROs were identified. One hundred twenty-six (85%) of these PROs measured Health-Related Quality of Life (HRQL), 10 (7%) measured QoL/Utilities, 9 (6%) measured Symptoms, 2 (1%) measured Activities of Daily Living and 1 (1%) was categorized as other. Within the HRQL measures, 35 (28%) were ovarian cancer specific measures, 27 (21%) were cancer general measures, 6 (5%) were cancer treatment specific, 2 (2%) were generic measures and 1 (1%) was chemotherapy treatment specific. The remaining 55 (43%) HRQL endpoints were unspecified. **CONCLUSIONS:** PROs are included in ovarian cancer clinical studies approximately half the time, which is low compared to other disease areas. The majority of measures assess HRQL and are specific to ovarian cancer. Including HRQL in ovarian cancer studies can support the value of progression free survival to patients. PROs can be used to show the value of new ovarian cancer drug therapies.

PCN123

DOES THE GENERIC CANCER OUTCOME MEASURE EORTC QLQ-C30 WORK IN MYELOFIBROSIS?

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OBJECTIVES: The EORTC QLQ-C30 is a validated patient reported outcome measure for cancer patients but there is limited evidence on its validity in Myelofibrosis (MF), a rare but serious bone-marrow cancer. This study aimed to provide evidence of its validity in MF. **METHODS:** QLQ-C30 was compared to MF specific measures (MF-SAF 2.0 and FACT-Lym) using trial data of MF patients (COMFORT I (n=309) and COMFORT II (n=219)). Convergent validity based on correlation analysis, known group analysis based on MF specific measures using Cohen's d effect size (ES) and responsiveness based on standardised response mean (SRM) were undertaken. **RESULTS:** QLQ-C30 dimensions (physical, role, emotional and social functioning, pain and fatigue) were strongly correlated (ρ>0.5) with equivalent items/dimensions in the MF-SAF and FACT-Lym but all QLQ_C30 dimensions were weakly correlated (ρ<0.3) to MF symptoms such as weight loss, itching and night sweats. Most QLQ-C30 dimensions were able to discriminate between MF-SAF (scores 0-10; 11-20; 21-30; 31-60) with better discrimination for the mild severity low score groups (0.2<ES<0.7) compared to high score groups (ES<0.2) who had higher severity and the FACT-Lym (scores 0-30; 31-40; 41-50; 51-60) groups. SRMs were <0.2 for most QLQ-C30 dimensions including pain but >0.2 for MF-SAF and